

REMARKS

This is in response to the Official Action of October 21, 2004 for this application. A Petition under 37 CFR 1.137(b) for revival of the above-captioned unintentionally abandoned application is enclosed.

Claims 1-67 have been rejected as allegedly not fulfilling the written description requirement in view of the recitation "sertraline having a solubility in pure water of greater than 10 mgA/ml".

In response, purely to expedite prosecution, claims 1-67 have been cancelled. New independent claim 68 and claims dependent thereon and new independent claim 79 are shown on page 3 of this response. The quoted limitation is not present in claims 68 and 79, and limitations that are present in claims 68 and 79 that were not present in cancelled claim 1 are supported by the specification as originally filed. Accordingly, claims 68 and 79, and claims dependent thereon, fulfill the written description requirement.

Claims 1-67 have been rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite for "failing to particularly point out and distinctly claim" the subject matter which applicant regards as the invention in view of the recitation "...but for the inclusion..." in claim 1. The same limitation appears in new Claim 68 and 79.

It is respectfully submitted, however, that the recitation "...but for the inclusion..." is not indefinite. One skilled in the art would readily understand that, in the claimed invention, the amount of the solubilizing agent is such that the concentration of dissolved sertraline in the composition containing the solubilizing agent is 1.5 times higher than the concentration of dissolved sertraline would be in a composition not containing the solubilizing agent but otherwise identical. Accordingly, claim 68, claims dependent thereon, and claim 79 do not fail to "particularly point out and distinctly claim" the invention. The rejection under 35 U.S.C. 112, second paragraph should therefore be withdrawn.

Claims 1-67 have been rejected under the doctrine of obviousness-double patenting as allegedly obvious over claims 19-22 of US 4,536,518 (Welch et al.). The Office Action alleges that "although the conflicting claims are not identical, they are not patentably distinct from each other because the method for combating mental depression in a mentally depressed subject by using sertraline has been taught by the reference. Presently claimed invention is drawn to a composition and method of use of the same compound."

It is respectfully submitted, however, that there is nothing in claims 19-22 of Welch et al. that discloses or suggests the invention claimed in new Claim 68 and claims dependent thereon and in new claim 79. Aside from the fact that claims 19-22 are directed to a method, while all the new claims are directed to a composition, claims 19-22 of Welch et al. do not disclose or suggest the invention of new claim 68 and claims dependent thereon and of new claim 79. For example, there is nothing in claims 19-22 of Welch et al., nor is there anything anywhere in Welch et al., that discloses or suggests the limitation, expressly recited in claims 68 and 79, "an amount of solubilizing agent sufficient to produce a concentration of dissolved sertraline in a use environment containing chloride ions which is 1.5 times higher than the concentration effected by a comparative composition of matter identical thereto but for the inclusion of said solubilizing agent." Nothing in Welch et al. even discloses or suggests the use of solubilizing agents at all, much less a solubilizing agent in an amount recited in claim 68 and 79. For at least this reason, the obviousness-double patenting rejection of Claim 68 (and all claims dependent thereon) and 79 over claims 19-22 of Welch et al. is conclusory and inappropriate, and it should be withdrawn.

Claims 1-67 have been rejected under 35 U.S.C. 102(e) as allegedly anticipated by Welch et al., which teaches sertraline and its use for the treatment of depression. The Office Action alleges that the entire document, "especially 39-65, col. 2; lines 17-49, col. 6; lines 22-65, col. 7; lines 10-20, col. 8, the examples and the claims", teaches the instant invention.

It is respectfully submitted, however, that there is nothing in Welch et al. that discloses or suggests the invention claimed in new Claim 68 and claims dependent thereon and in claim 79. There is no disclosure in 39-65, col. 2; lines 17-49, col. 6; lines 22-65, col. 7; lines 10-20, col. 8, the examples; and the claims, in Welch et al. – or anywhere else in Welch et al. – of the limitation, expressly recited in claim 68 and 79, “an amount of solubilizing agent sufficient to produce a concentration of dissolved sertraline in a use environment containing chloride ions which is 1.5 times higher than the concentration effected by a comparative composition of matter identical thereto but for the inclusion of said solubilizing agent.” Nothing in Welch et al. even discloses or suggests the use of solubilizing agents at all, much less a solubilizing agent in an amount recited in claim 68 and 79. For at least this reason, the rejection of Claim 68 (and all claims dependent thereon) and 79 as allegedly anticipated under 35 USC 102(e) by Welch et al. is conclusory and inappropriate, and it should be withdrawn.

Claims 1-67 have been rejected under 35 U.S.C. 103(a) as allegedly obvious over US Patent No. 5,130,338 (Bacopoulos) and Welch et al. The Office Action alleges that both references teach the composition and use of sertraline, “which embraces the instant invention. See the entire documents especially: Bacopoulos: lines 9-68, col. 1; lines 21-68, col. 2; lines 4-36, col. 3 and claims. Welch Jr. et al.: lines 39-65, col. 2; lines 17-49, col. 6; lines 22-65, col. 7; lines 10-20, col. 8, examples and claims. It would have been obvious to one skilled in the art to prepare additional beneficial composition of sertraline because prior art teaches the composition and method of use of the same compound and its salts. Nothing unobvious is seen in making the compositions of sertraline or its pharmaceutical salts as presently claimed.”

It is respectfully submitted, however, that there is nothing in either Bacopoulos or Welch et al. – or the combination thereof - that discloses or suggests the invention claimed in new Claim 68 and claims dependent thereon or in new claim 79. As previously discussed, there is no disclosure in 39-65, col. 2; lines 17-49, col. 6; lines 22-65, col. 7; lines 10-20, col. 8, the examples; and the claims, in Welch et al. – or anywhere else in Welch et al. – of the limitation, expressly recited in claim 68 and in new claim 79, “an amount

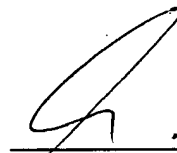
of solubilizing agent sufficient to produce a concentration of dissolved sertraline in a use environment containing chloride ions which is 1.5 times higher than the concentration effected by a comparative composition of matter identical thereto but for the inclusion of said solubilizing agent." Nothing in Welch et al. even discloses or suggests the use of solubilizing agents at all, much less a solubilizing agent in an amount recited in claim 68 and in claim 79. The same applies in toto to Bacopoulos, which is directed to the treatment a chemical dependency or addiction. Bacopoulos, like Welch et al. utterly fails to disclose or suggest the use of solubilizing agents at all, much less a solubilizing agent in an amount recited in claim 68. For at least the foregoing reasons, the rejection of Claim 68 (and all claims dependent thereon) and of claim 79 as allegedly obvious over 35 USC 103(a) Welch et al., over Bacopoulos, or over the combination of the two references, is conclusory and inappropriate, and it should be withdrawn.

In view of the foregoing, allowance of all pending claims in the application is respectfully requested.

The Commissioner is hereby authorized to charge any fees required under 37 C.F.R. §§1.16 and 1.17 or to credit any overpayment to Deposit Account No. 16-1445. Two copies of this paper are enclosed.

Respectfully submitted,

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Andrea E. Dorigo

Attorney for Applicant(s)

Reg. No. 47,532

Pfizer, Inc.  
Patent Department, 5th Floor  
150 East 42nd Street  
New York, NY 10017-5755  
(212) 733-1898